**TDMS No.** 88123 - 07 Test Type: CHRONIC P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

FORMAMIDE

**CAS Number:** 75-12-7

Pathologist: RYAN, M. - Blackshear, P. Species/Strain: MICE/B6C3F1

F1\_M3

C Number:

Route: GAVAGE

C88123B

Lock Date:

05/24/2004

Cage Range:

ALL

**Date Range:** 

ALL

**Reasons For Removal:** 

ALL

**Removal Date Range:** 

ALL

**Treatment Groups:** 

Include ALL

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

FORMAMIDE

**CAS Number:** 75-12-7

**Species/Strain:** MICE/B6C3F1 **Pathologist:** RYAN, M. - Blackshear, P.

TDMS No. 88123 - 07 Test Type: CHRONIC

Route: GAVAGE

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Disposition Summary					
Animals Initially in Study	50	50	50	50	
Early Deaths					
Moribund Sacrifice	4	8	6	14	
Natural Death Survivors	7		8	3	
Terminal Sacrifice	39	42	36	33	
Animals Examined Microscopically	50	50	50	50	
LIMENTARY SYSTEM					
Esophagus	(50)	(50)	(50)	(50)	
Artery, Inflammation, Chronic			1 (2%)		
Muscularis, Inflammation, Chronic	1 (2%)				
Gallbladder	(45)	(48)	(45)	(46)	
Cyst		1 (2%)			
Inflammation, Chronic		1 (2%)	1 (2%)	3 (7%)	
Ulcer				1 (2%)	
Epithelium, Cytoplasmic Alteration		1 (2%)	0 (40()	2 (4%)	
Epithelium, Hyperplasia	(50)	1 (2%)	2 (4%)	(50)	
Intestine Large, Cecum	(50)	(50)	(50)	(50)	
Edema		1 (2%)	4 (20()		
Hemorrhage Artery, Inflammation, Chronic			1 (2%) 1 (2%)		
Intestine Large, Colon	(50)	(50)	(50)	(50)	
Hemorrhage	(30)	(50)	1 (2%)	(30)	
Artery, Inflammation, Chronic	1 (2%)		1 (270)		
Intestine Large, Rectum	(50)	(50)	(50)	(50)	
Artery, Inflammation, Chronic	(00)	1 (2%)	(00)	(00)	
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	
Artery, Inflammation, Chronic	1 (2%)	(33)	(33)	(55)	
Epithelium, Hyperplasia, Focal	(= / 5/			1 (2%)	
Intestine Small, Ileum	(50)	(50)	(50)	(50)	
Intestine Small, Jejunum	(50)	(50)	(50)	(50)	
Inflammation, Granulomatous	,	1 (2%)	,	,	
Inflammation, Chronic		•		1 (2%)	
Peyer's Patch, Hyperplasia, Lymphoid	2 (4%)			1 (2%)	
Liver	(50)	(50)	(50)	(50)	

a - Number of animals examined microscopically at site and number of animals with lesion

TDMS No. 88123 - 07 Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

# FORMAMIDE CAS Number: 75-12-7

CAS Number: 75-12-7
Pathologist: RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Angiectasis			1 (2%)		
Basophilic Focus	2 (4%)	4 (8%)	3 (6%)	4 (8%)	
Clear Cell Focus	29 (58%)	27 (54%)	21 (42%)	8 (16%)	
Eosinophilic Focus	16 (32%)	21 (42%)	14 (28%)	9 (18%)	
Fatty Change	31 (62%)	25 (50%)	15 (30%)	1 (2%)	
Fibrosis	0: (0270)	20 (0070)	10 (0070)	1 (2%)	
Hematopoietic Cell Proliferation	1 (2%)			(270)	
Hepatodiaphragmatic Nodule	1 (270)			1 (2%)	
Inflammation, Acute	1 (2%)			1 (2%)	
Inflammation, Chronic	16 (32%)	16 (32%)	11 (22%)	15 (30%)	
Mineralization	1 (2%)	1 (2%)	11 (2270)	10 (0070)	
Mixed Cell Focus	10 (20%)	12 (24%)	13 (26%)	11 (22%)	
Necrosis	5 (10%)	9 (18%)	7 (14%)	11 (22%)	
Tension Lipidosis	4 (8%)	5 (10%)	1 (2%)	6 (12%)	
Bile Duct, Dilatation	4 (070)	1 (2%)	1 (270)	0 (1270)	
Bile Duct, Hyperplasia		1 (2%)			
Centrilobular, Degeneration	1 (2%)	1 (270)			
Centrilobular, Necrosis	1 (2%)			1 (2%)	
Serosa, Hyperplasia	1 (270)	1 (2%)		1 (270)	
Vein, Thrombosis		1 (270)		1 (2%)	
Mesentery	(3)	(1)	(1)	(1)	
Inflammation, Chronic	1 (33%)	(1)	(1)	(1)	
Artery, Inflammation, Chronic	1 (33%)		1 (100%)		
Fat, Necrosis	1 (33%)	1 (100%)	1 (10078)		
Oral Mucosa	(7)	(5)	(5)	(7)	
Inflammation, Chronic	(1)	(5)	(3)	1 (14%)	
Gingival, Inflammation, Chronic	7 (100%)	5 (100%)	5 (100%)	6 (86%)	
Pancreas	(50)	(50)	(50)	(50)	
Acinus, Atrophy	1 (2%)	3 (6%)	(30)	2 (4%)	
Acinus, Atrophy Acinus, Cytoplasmic Alteration	1 (2/6)	1 (2%)	1 (2%)	1 (2%)	
Duct, Cyst		1 (270)	1 (2%)	1 (2%)	
Duct, Inflammation, Chronic		1 (2%)	1 (276)	1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)	
Inflammation, Granulomatous	1 (2%)	(50)	(50)	(50)	
Artery, Parotid Gland, Inflammation, Chronic	I (∠70)		1 (2%)		
Artery, Parotid Gland, Inflammation, Chronic Artery, Parotid Gland, Mineralization			1 (2%)	1 (20/)	
Parotid Gland, Atrophy			I (270)	1 (2%) 1 (2%)	
Parotid Gland, Atrophy Stomach, Forestomach	(50)	(50)	(FO)		
	(50)	(50)	(50)	(50)	
Hemorrhage	4 (20/)		1 (2%)		
Inflammation, Chronic Ulcer	1 (2%) 1 (2%)		1 (2%)	1 (2%)	

FORMAMIDE

**CAS Number:** 75-12-7

**Species/Strain:** MICE/B6C3F1 **Pathologist:** RYAN, M. - Blackshear, P.

**TDMS No.** 88123 - 07

Test Type: CHRONIC

Route: GAVAGE

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Artery, Inflammation, Chronic Epithelium, Hyperplasia, Focal Epithelium, Vacuolization Cytoplasmic	1 (2%) 1 (2%)	1 (2%)	1 (2%)		
Stomach, Glandular Hemorrhage, Acute	(50)	(50) 1 (2%)	(50)	(50)	
Inflammation, Chronic Mineralization		1 (270)	4 (8%) 1 (2%)	1 (2%)	
Ulcer Epithelium, Glands, Ectasia		1 (2%)	1 (2%)	3 (6%)	
Epithelium, Glands, Hyperplasia, Focal Epithelium, Hyperplasia, Focal		1 (2%)	1 (2%)		
Glands, Ectasia Tooth	(15)	1 (2%) (14)	2 (4%) (9)	2 (4%) (2)	
Dysplasia Malformation	2 (13%) 14 (93%)	1 (7%) 13 (93%)	2 (22%) 7 (78%)	2 (100%)	
CARDIOVASCULAR SYSTEM					
Blood Vessel Aorta, Inflammation, Chronic	(50) 1 (2%)	(50)	(50)	(50)	
Heart Thrombosis	(50)	(50)	(50)	(50) 1 (2%)	
Artery, Inflammation, Chronic Atrium, Thrombosis Epicardium, Hyperplasia Epicardium, Infiltration Cellular, Mononuclear	1 (2%) 1 (2%) 1 (2%) 1 (2%)	1 (2%) 1 (2%)	2 (4%)	3 (6%)	
Cell Myocardium, Infiltration Cellular,	9 (18%)	10 (20%)	2 (4%)	12 (24%)	
Mononuclear Cell Myocardium, Mineralization Myocardium, Necrosis Myocardium, Necrosis, Focal	3 (6%)	1 (2%) 1 (2%)	2 (4%) 1 (2%)	2 (4%) 4 (8%)	
Nerve, Inflammation, Chronic Ventricle, Atrophy		<i>、                                    </i>	1 (2%)	1 (2%)	
ENDOCRINE SYSTEM					
Adrenal Cortex Angiectasis	(50)	(50) 1 (2%)	(49) 1 (2%)	(50) 1 (2%)	
Hyperplasia	2 (4%)	1 (2/0)	1 (2/0)	2 (4%)	

a - Number of animals examined microscopically at site and number of animals with lesion

FORMAMIDE

**CAS Number:** 75-12-7

**Species/Strain:** MICE/B6C3F1 **Pathologist:** RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Hypertrophy	15 (30%)	17 (34%)	17 (35%)	13 (26%)	
Pigmentation	1 (2%)	( /	(,	2 (4%)	
Vacuolization Cytoplasmic	( /			1 (2%)	
Vacuolization Cytoplasmic, Focal	17 (34%)	14 (28%)	11 (22%)	16 (32%)	
Subcapsular, Hyperplasia	50 (100%)	49 (98%)	42 (86%)	45 (90%)	
Subcapsular, Hypertrophy, Focal	1 (2%)	,	,	,	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Hyperplasia, Focal	2 (4%)	1 (2%)	1 (2%)	3 (6%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	35 (70%)	24 (48%)	24 (48%)	9 (18%)	
Parathyroid Gland	(43)	(39)	(46)	(47)	
Right, Atrophy				1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(49)	
Angiectasis	1 (2%)				
Cyst	5 (10%)	2 (4%)	2 (4%)	2 (4%)	
Pars Distalis, Hyperplasia, Focal	3 (6%)	4 (8%)	1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(50)	
Cyst	2 (4%)	3 (6%)	2 (4%)	5 (10%)	
Inflammation, Granulomatous	1 (2%)				
Inflammation, Chronic		1 (2%)		1 (2%)	
C-cell, Hyperplasia				1 (2%)	
Follicle, Hyperplasia	1 (2%)				
Follicle, Hyperplasia, Focal	12 (24%)	15 (30%)	8 (16%)	8 (16%)	

### **GENERAL BODY SYSTEM**

None

# **GENITAL SYSTEM**

TDMS No. 88123 - 07 Test Type: CHRONIC

Route: GAVAGE

Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm	1 (2%)	1 (2%)	,	3 (6%)
Inflammation, Chronic	1 (2%)	, ,		1 (2%)
Artery, Inflammation, Chronic		1 (2%)		
Preputial Gland	(50)	(50)	(50)	(50)
Cyst	19 (38%)	11 (22%)	11 (22%)	10 (20%)
Infiltration Cellular, Lymphoid			1 (2%)	
Infiltration Cellular, Chronic				1 (2%)
Inflammation, Suppurative				1 (2%)
Inflammation, Granulomatous	1 (2%)	1 (2%)		

a - Number of animals examined microscopically at site and number of animals with lesion

**TDMS No.** 88123 - 07 Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

FORMAMIDE

**CAS Number:** 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Inflammation, Chronic	1 (2%)	4 (8%)		1 (2%)	
Duct, Cyst Prostate	(50)	1 (2%) (50)	(50)	(50)	
Infiltration Cellular, Lymphoid Inflammation, Suppurative Inflammation, Chronic	1 (2%)	1 (2%) 1 (2%)	1 (2%) 1 (2%)	1 (2%)	
Seminal Vesicle Atrophy	(50)	(50)	(50)	(50) 2 (4%)	
Fibrosis Inflammation, Suppurative	1 (2%) 1 (2%)		1 (2%)	2 (470)	
Inflammation, Chronic Testes Granuloma Sperm	(50)	1 (2%) (50)	(50)	(50) 1 (2%)	
Artery, Inflammation, Chronic Artery, Mineralization	1 (2%)	2 (4%)	1 (2%) 5 (10%)	35 (70%)	
Artery, Thrombosis Germinal Epithelium, Degeneration Germinal Epithelium, Inflammation, Chronic	1 (2%)	4 (8%)	1 (2%) 1 (2%)	4 (8%) 1 (2%)	
Germinal Epithelium, Mineralization Tunic, Inflammation, Chronic Tunic, Mineralization	1 (2%) 1 (2%)	1 (2%)	1 (2%) 5 (10%)	1 (2%) 27 (54%)	
HEMATOPOIETIC SYSTEM	1 (270)		3 (1070)	21 (0170)	
Bone Marrow Hyperplasia Lymph Node	(50) 34 (68%) (4)	(50) 39 (78%) (2)	(50) 35 (70%) (1)	(50) 34 (68%) (1)	
Bronchial, Hyperplasia, Lymphoid Lumbar, Hyperplasia, Lymphoid Mediastinal, Hyperplasia, Lymphoid Pancreatic, Hyperplasia	1 (25%) 1 (25%) 2 (50%)	1 (50%)			
Renal, Hyperplasia, Lymphoid Lymph Node, Mandibular Atrophy	2 (50%) (49) 11 (22%)	(48) 5 (10%)	(49) 6 (12%)	(48) 13 (27%)	
Hematopoietic Cell Proliferation Hyperplasia, Lymphoid Necrosis, Lymphoid	1 (2%) 2 (4%) 2 (4%)	5 (10%)	5 (10%)	2 (4%) 1 (2%)	
Lymph Node, Mesenteric Atrophy Hyperplasia, Lymphoid	(50) 10 (20%) 4 (8%)	(47) 3 (6%) 1 (2%)	(50) 6 (12%) 4 (8%)	(49) 14 (29%)	
Necrosis, Lymphoid	1 (2%)	. (= /0)	1 (2%)	1 (2%)	

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TDMS No. 88123 - 07 Test Type: CHRONIC

Route: GAVAGE
Species/Strain: MICE/B6C3F1

FORMAMIDE

CAS Number: 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Spleen Atrophy Hematopoietic Cell Proliferation	(50) 2 (4%) 14 (28%)	(50) 6 (12%) 14 (28%)	(50) 3 (6%) 20 (40%)	(50) 7 (14%) 28 (56%)	
Hyperplasia, Plasma Cell Lymphoid Follicle, Hyperplasia Lymphoid Follicle, Necrosis	1 (2%) 4 (8%) 1 (2%)	1 (2%)	4 (8%)		
Thymus Atrophy Cyst Ectopic Parathyroid Gland Hyperplasia, Lymphoid	(47) 41 (87%) 19 (40%) 1 (2%)	(46) 39 (85%) 9 (20%)	(50) 37 (74%) 15 (30%) 1 (2%) 2 (4%)	(46) 44 (96%) 9 (20%)	
Necrosis Epithelial Cell, Hyperplasia	1 (2%)		1 (2%)		
INTEGUMENTARY SYSTEM					
Skin Ulcer Subcutaneous Tissue, Edema Subcutaneous Tissue, Inflammation, Chronic	(50) 1 (2%)	(50)	(50)	(50) 3 (6%) 1 (2%)	
Subcutaneous Tissue, Necrosis	1 (270)		1 (2%)		
MUSCULOSKELETAL SYSTEM					
Bone Hyperostosis Cranium, Hyperplasia	(50) 1 (2%)	(50) 2 (4%) 1 (2%)	(50) 2 (4%)	(50) 3 (6%)	
Skeletal Muscle Inflammation, Granulomatous	(1) 1 (100%)	(1)	(0)	(2)	
NERVOUS SYSTEM					
Brain Compression Cyst Epithelial Inclusion	(50) 1 (2%) 1 (2%)	(50)	(50)	(50)	
Hemorrhage, Acute Hydrocephalus Necrosis	1 (2%)	1 (2%) 1 (2%)			
Artery, Inflammation, Chronic Meninges, Ventricle, Inflammation,	1 (2%)	1 (2%)	1 (2%)		

a - Number of animals examined microscopically at site and number of animals with lesion

Test Type: CHRONIC

Route: GAVAGE

**TDMS No.** 88123 - 07

Species/Strain: MICE/B6C3F1

FORMAMIDE

**CAS Number:** 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Granulomatous		4 (00()			
Meninges, Infiltration Cellular, Lymphocyte		1 (2%)			
Vein, Infiltration Cellular, Mononuclear Cell	(0)	1 (2%)	(4)	(0)	
Peripheral Nerve	(0)	(0)	(1)	(0)	
Axon, Degeneration	(5)	(2)	1 (100%)	(2)	
Spinal Cord	(0)	(0)	(1)	(0)	
Hemorrhage			1 (100%)		
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	
Fibrosis	1 (2%)	(/	(/	()	
Inflammation, Chronic	· \='\"/		3 (6%)	1 (2%)	
Metaplasia, Osseous			2 (4%)	. (=/5)	
Alveolar Epithelium, Hyperplasia	2 (4%)	1 (2%)	4 (8%)	2 (4%)	
Alveolus, Infiltration Cellular, Histiocyte	1 (2%)	. (= /0)	1 (2%)	8 (16%)	
Arteriole, Thrombosis	1 (2%)		1 (270)	0 (1070)	
Artery, Mineralization	1 (2%)				
Bronchus, Hypertrophy	1 (2%)				
Serosa, Inflammation, Chronic	1 (270)			1 (2%)	
Nose	(50)	(50)	(50)	(50)	
Inflammation, Suppurative	4 (8%)	4 (8%)	1 (2%)	1 (2%)	
Inflammation, Suppurative	4 (6 %)	2 (4%)	1 (2%)	1 (2%)	
Polyp, Inflammatory	1 (2%)	2 (4%) 1 (2%)	1 (2%)	1 (2%)	
	1 (2%)	1 (2%)	1 (2%)	4 (20/)	
Glands, Hyperplasia	1 (20/)			1 (2%)	
Glands, Hyperplasia, Focal	1 (2%)	4 (20()	4 (20()		
Glands, Inflammation, Suppurative	4 (8%)	1 (2%)	1 (2%)	0 (40()	
Nasolacrimal Duct, Infiltration Cellular,	2 (4%)	5 (10%)	2 (4%)	2 (4%)	
Polymorphonuclear				4 (00()	
Nasopharyngeal Duct, Inflammation, Chronic	4 (00()			1 (2%)	
Olfactory Epithelium, Amyloid Deposition	1 (2%)	= (400()	4 (004)	0 (404)	
Olfactory Epithelium, Atrophy, Focal	8 (16%)	5 (10%)	1 (2%)	2 (4%)	
Olfactory Epithelium, Metaplasia	1 (2%)				
Olfactory Epithelium, Metaplasia, Focal		1 (2%)			
Respiratory Epithelium, Atrophy, Focal		2 (4%)			
Respiratory Epithelium, Hyperplasia, Focal	1 (2%)	1 (2%)	1 (2%)		
Respiratory Epithelium, Metaplasia,		1 (2%)			
Squamous					
Vomeronasal Organ, Infiltration Cellular,	2 (4%)	10 (20%)	3 (6%)	4 (8%)	
Polymorphonuclear					
Pleura	(1)	(0)	(0)	(0)	

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**TDMS No.** 88123 - 07 Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

FORMAMIDE

**CAS Number:** 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Hyperplasia	1 (100%)				
SPECIAL SENSES SYSTEM					
Eye Degeneration Anterior Chamber, Inflammation, Suppurative	(50)	(50)	(50)	(50) 1 (2%) 1 (2%)	
Cornea, Inflammation, Chronic Harderian Gland Hyperplasia, Focal	3 (6%) (50) 4 (8%)	(50) 8 (16%)	2 (4%) (50) 5 (10%)	1 (2%) (50) 10 (20%)	
URINARY SYSTEM					
Kidney Casts Protein	(50) 1 (2%)	(50)	(50)	(50)	
Fibrosis, Focal Infarct Inflammation, Suppurative	1 (2%)	1 (2%)	1 (2%) 3 (6%)	1 (2%)	
Inflammation, Chronic Metaplasia, Osseous Mineralization Necrosis	1 (2%) 16 (32%)	2 (4%) 1 (2%) 15 (30%)	3 (6%) 2 (4%)	1 (2%) 4 (8%) 5 (10%) 1 (2%)	
Nephropathy Artery, Inflammation, Chronic Glomerulus, Inflammation, Chronic Glomerulus, Necrosis, Fibrinoid	43 (86%) 2 (4%) 1 (2%) 1 (2%)	46 (92%) 1 (2%)	41 (82%) 1 (2%)	45 (90%)	
Papilla, Necrosis Pelvis, Inflammation, Suppurative Renal Tubule, Accumulation, Hyaline Droplet	1 (2%) 1 (2%) 1 (2%)			2 (4%)	
Renal Tubule, Cyst Renal Tubule, Hyperplasia Renal Tubule, Mineralization	8 (16%) 1 (2%)	5 (10%) 2 (4%)	4 (8%) 5 (10%) 1 (2%)	5 (10%) 1 (2%)	
Vein, Infiltration Cellular, Lymphocyte Urinary Bladder Infiltration Cellular, Lymphoid Inflammation, Suppurative	(50) 1 (2%) 1 (2%)	1 (2%) (50)	(50) 1 (2%)	(50)	
Inflammation, Chronic Artery, Inflammation, Chronic Artery, Mineralization	1 (2%) 1 (2%)	2 (4%)	1 (2%)	1 (2%)	

a - Number of animals examined microscopically at site and number of animals with lesion

TDMS No. 88123 - 07
Test Type: CHRONIC

Test Type: CHRONIC Route: GAVAGE

Species/Strain: MICE/B6C3F1

# P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

**FORMAMIDE** 

**CAS Number:** 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Transitional Epithelium, Hyperplasia	1 (2%)				

\*\*\* END OF MALE \*\*\*

**TDMS No.** 88123 - 07

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

FORMAMIDE **CAS Number:** 75-12-7 Pathologist: RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Disposition Summary					
Animals Initially in Study Early Deaths	50	50	50	50	
Dosing Accident Moribund Sacrifice Natural Death Survivors	7 5	8 3	1 8 10	8 3	
Natural Death Terminal Sacrifice Animals Examined Microscopically	38 50	1 38 50	31 50	39 50	
ALIMENTARY SYSTEM					
Esophagus Inflammation, Suppurative	(50)	(50)	(50) 1 (2%)	(50)	
Perforation Gallbladder Cyst Inflammation, Chronic	(47) 1 (2%) 1 (2%)	(45)	1 (2%) (46)	(49)	
Epithelium, Cytoplasmic Alteration Intestine Large, Cecum Edema	(49) 1 (2%)	(50)	(50)	1 (2%) (50)	
Lymphoid Tissue, Hyperplasia, Lymphoid Intestine Large, Colon Intestine Large, Rectum	(50) (50)	(50) (50)	1 (2%) (50) (50)	(50) (50)	
Serosa, Inflammation, Chronic Intestine Small, Duodenum Inflammation, Chronic Epithelium, Hyperplasia, Focal	(50) 1 (2%) 1 (2%)	(50)	1 (2%) (50)	(50)	
Intestine Small, Ileum Epithelium, Cyst	(50) 1 (2%)	(50)	(50)	(50)	
Intestine Small, Jejunum Artery, Peyer's Patch, Mineralization	(50)	(50)	(50) 1 (2%)	(50)	
Epithelium, Hyperplasia, Focal Liver Angiectasis	(50)	(50)	(50) 2 (4%)	1 (2%) (50)	
Basophilic Focus Clear Cell Focus	3 (6%)	2 (4%)	1 (2%) 2 (4%)	2 (4%) 2 (4%)	

a - Number of animals examined microscopically at site and number of animals with lesion

**TDMS No.** 88123 - 07 Route: GAVAGE

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

FORMAMIDE **CAS Number:** 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Eosinophilic Focus	12 (24%)	15 (30%)	8 (16%)	7 (14%)	
Fatty Change	6 (12%)	7 (14%)	4 (8%)	2 (4%)	
Hematopoietic Cell Proliferation	3 (6%)	4 (8%)	1 (2%)	1 (2%)	
Infarct	- (-,-)	( ( ) )	1 (2%)	(= / - /	
Inflammation, Chronic	29 (58%)	27 (54%)	21 (42%)	21 (42%)	
Mineralization	_= (==,=)	_: (* : / *)	_: (:=/:)	1 (2%)	
Mixed Cell Focus	4 (8%)	5 (10%)	4 (8%)	6 (12%)	
Necrosis	1 (2%)	3 (1373)	. (0,0)	2 (4%)	
Tension Lipidosis	3 (6%)	9 (18%)	5 (10%)	6 (12%)	
Centrilobular, Necrosis	3 (373)	3 (1373)	1 (2%)	3 (12/3)	
Centrilobular, Vacuolization Cytoplasmic	1 (2%)		1 (270)		
Mesentery	(8)	(3)	(8)	(2)	
Fat, Necrosis	5 (63%)	3 (100%)	8 (100%)	2 (100%)	
Oral Mucosa	(1)	(0)	(0)	(0)	
Gingival, Inflammation, Chronic	1 (100%)	(0)	(0)	(0)	
Pancreas	(49)	(49)	(50)	(50)	
Hyperplasia, Lymphoid	(40)	(43)	1 (2%)	(00)	
Inflammation, Chronic			2 (4%)		
Acinus, Atrophy		1 (2%)	3 (6%)	2 (4%)	
Acinus, Cytoplasmic Alteration	1 (2%)	1 (270)	3 (070)	1 (2%)	
Artery, Thrombosis	1 (270)		1 (2%)	1 (270)	
Duct, Cyst			1 (2%)	3 (6%)	
Duct, Cytoplasmic Alteration			1 (276)	1 (2%)	
Duct, Cytopiasmic Alteration  Duct, Inflammation, Chronic	1 (2%)		1 (2%)	1 (2/0)	
Salivary Glands	(49)	(50)	(50)	(50)	
Atrophy, Diffuse	(49)	(50)	(30)	1 (2%)	
Parotid Gland, Atrophy		1 (2%)	1 (2%)	1 (270)	
Stomach, Forestomach	(50)			(50)	
	(50)	(50)	(50)	(50)	
Inflammation, Chronic	1 (2%)			4 (20/)	
Epithelium, Hyperplasia	1 (2%)	(50)	(50)	1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Inflammation, Chronic	1 (2%)	1 (2%)		1 (2%)	
Ulcer	4 (20/)	1 (2%)		4 (20/)	
Epithelium, Glands, Cytoplasmic Alteration	1 (2%)			1 (2%)	
Epithelium, Glands, Hyperplasia	4 (20/)			1 (2%)	
Glands, Ectasia	1 (2%)				
Glands, Hyperplasia	1 (2%)	(0)	(0)	(4)	
Tooth	(0)	(0)	(0)	(1)	
Malformation				1 (100%)	

FORMAMIDE

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TDMS No. 88123 - 07 Test Type: CHRONIC

Route: GAVAGE

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B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
CARDIOVASCULAR SYSTEM					
Heart	(50)	(50)	(50)	(50)	
Artery, Inflammation, Chronic	2 (4%)				
Atrium, Thrombosis			1 (2%)	1 (2%)	
Coronary Artery, Inflammation, Chronic	1 (2%)	- ( )	. (221)	- (()	
Myocardium, Infiltration Cellular,	2 (4%)	7 (14%)	4 (8%)	3 (6%)	
Mononuclear Cell		0 (00()	4 (00()		
Myocardium, Mineralization		3 (6%)	1 (2%)		
Myocardium, Necrosis			1 (2%)	4 (00()	
Ventricle, Thrombosis				1 (2%)	
ENDOCRINE SYSTEM					
Adrenal Cortex	(49)	(50)	(49)	(50)	
Angiectasis		1 (2%)			
Atrophy				1 (2%)	
Hematopoietic Cell Proliferation	1 (2%)	1 (2%)			
Hyperplasia		2 (4%)		1 (2%)	
Hypertrophy	1 (2%)	1 (2%)	4 (8%)		
Pigmentation		3 (6%)			
Vacuolization Cytoplasmic, Focal	3 (6%)		2 (4%)		
Subcapsular, Hyperplasia	49 (100%)	49 (98%)	48 (98%)	49 (98%)	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Angiectasis		1 (2%)			
Hyperplasia, Focal	1 (2%)	4 (8%)	1 (2%)	2 (4%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	1 (2%)	1 (2%)	4 (8%)		
Parathyroid Gland	(42)	(32)	(35)	(42)	
Cyst	1 (2%)			2 (5%)	
Pituitary Gland	(50)	(50)	(49)	(50)	
Angiectasis	2 (4%)	1 (2%)			
Cyst	3 (6%)	4 (8%)		1 (2%)	
Fibrosis		1 (2%)			
Hemorrhage, Chronic		1 (2%)		10 (05-1)	
Pars Distalis, Hyperplasia, Focal	11 (22%)	11 (22%)	10 (20%)	10 (20%)	
Pars Intermedia, Hyperplasia, Focal	1 (2%)	(F-1)	1 (2%)	1 (2%)	
Thyroid Gland	(49)	(50)	(50)	(50)	
Cyst	1 (2%)	1 (2%)	2 (4%)		
Infiltration Cellular, Lymphoid		1 (2%)			

a - Number of animals examined microscopically at site and number of animals with lesion

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**TDMS No.** 88123 - 07

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B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Inflammation, Suppurative Inflammation, Granulomatous Inflammation, Chronic Follicle, Hyperplasia, Focal	1 (2%) 14 (29%)	2 (4%) 1 (2%) 6 (12%)	1 (2%) 10 (20%)	1 (2%) 5 (10%)	
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Clitoral Gland Duct, Cyst Ovary Angiectasis Cyst Mineralization Thrombosis Bilateral, Thrombosis Follicle, Atrophy Uterus Angiectasis Dilatation Inflammation, Suppurative Inflammation, Chronic Active Thrombosis Endometrium, Hyperplasia, Cystic	(50) (50) 2 (4%) 24 (48%) 1 (2%) 1 (2%) 33 (66%) (50) 1 (2%) 45 (90%)	(50) (50) 2 (4%) 19 (38%) 1 (2%) 1 (2%) 29 (58%) (50) 2 (4%) 1 (2%) 48 (96%)	(49) (50) 1 (2%) 11 (22%) 2 (4%) 35 (70%) (50) 2 (4%)  1 (2%) 45 (90%)	(50) 1 (2%) (49) 2 (4%) 23 (47%) 2 (4%) 37 (76%) (50) 1 (2%) 2 (4%) 1 (2%) 42 (84%)	
HEMATOPOIETIC SYSTEM  Bone Marrow	(50)	(50)	(50)	(50)	
Atrophy Hyperplasia Infiltration Cellular, Histiocyte Lymph Node Bronchial, Hyperplasia, Lymphoid Iliac, Necrosis Lumbar, Hematopoietic Cell Proliferation Lumbar, Hyperplasia, Lymphoid Mediastinal, Hematopoietic Cell Proliferation	(50) 8 (16%) 1 (2%) (8)  1 (13%) 1 (13%) 1 (13%)	(50) 10 (20%) (4) 1 (25%) 1 (25%)	(50) 13 (26%) (6)	(50) 1 (2%) 5 (10%) (5)	

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**CAS Number:** 75-12-7

**Species/Strain:** MICE/B6C3F1 **Pathologist:** RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006 Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Mediastinal, Hyperplasia, Lymphoid	2 (25%)				
Mediastinal, Inflammation, Chronic	2 (2070)		1 (17%)		
Renal, Hyperplasia, Lymphoid	1 (13%)		. (,-,		
Lymph Node, Mandibular	(49)	(50)	(50)	(50)	
Atrophy	3 (6%)	2 (4%)	6 (12%)	4 (8%)	
Hematopoietic Cell Proliferation	1 (2%)	1 (2%)	,	,	
Hyperplasia, Lymphoid	8 (16%)	( /	5 (10%)	6 (12%)	
Necrosis, Lymphoid	1 (2%)		1 (2%)	,	
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)	
Atrophy	7 (14%)	9 (18%)	8 (16%)	7 (14%)	
Hematopoietic Cell Proliferation	1 (2%)	- ( )	- ( /	(,	
Hyperplasia, Lymphoid	4 (8%)	1 (2%)	4 (8%)	3 (6%)	
Infiltration Cellular, Polymorphonuclear	()	( )	1 (2%)	- ()	
Inflammation, Suppurative			( /	1 (2%)	
Necrosis, Lymphoid	2 (4%)	1 (2%)	1 (2%)	(=73)	
Spleen	(50)	(49)	(49)	(50)	
Atrophy	1 (2%)	2 (4%)	1 (2%)	2 (4%)	
Hematopoietic Cell Proliferation	17 (34%)	17 (35%)	15 (31%)	8 (16%)	
Hyperplasia, Lymphoid	(	()	- (,	3 (6%)	
Hyperplasia, Plasma Cell	1 (2%)		1 (2%)	- ()	
Lymphoid Follicle, Hyperplasia	3 (6%)	4 (8%)	( /	2 (4%)	
Lymphoid Follicle, Necrosis	3 (6%)	()		1 (2%)	
Thymus	(49)	(50)	(49)	(50)	
Angiectasis	( - /	()	( - /	1 (2%)	
Atrophy	16 (33%)	19 (38%)	12 (24%)	17 (34%)	
Cyst	7 (14%)	9 (18%)	7 (14%)	(3-3-3)	
Hyperplasia, Lymphoid	9 (18%)	11 (22%)	7 (14%)	8 (16%)	
Necrosis, Lymphoid	1 (2%)	1 (2%)	1 (2%)	,	
TEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(50)	
Hyperplasia, Cystic	1 (2%)	1 (2%)			
Skin	(50)	(50)	(50)	(50)	
Cyst Epithelial Inclusion			1 (2%)		
Inflammation, Granulomatous			1 (2%)		
Ulcer			2 (4%)		

MUSCULOSKELETAL SYSTEM

**TDMS No.** 88123 - 07

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B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Bone	(50)	(50)	(50)	(50)	
Atrophy	0 (00()	0 (400()	0 (00()	1 (2%)	
Hyperostosis Skeletal Muscle	3 (6%) (2)	6 (12%) (5)	3 (6%) (5)	2 (4%)	
Fibrosis	(2)	3 (60%)	(5)	(0)	
Inflammation, Chronic		G (GG 70)	1 (20%)		
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Arteriole, Inflammation, Chronic	1 (2%)			. (224)	
Artery, Meninges, Inflammation, Chronic	4 (20/)	2 (40/)	4 (20/)	1 (2%)	
Hypothalamus, Compression Meninges, Infiltration Cellular, Lymphocyte	1 (2%) 2 (4%)	2 (4%)	1 (2%) 1 (2%)		
Vein, Infiltration Cellular, Lymphocyte	1 (2%)		1 (270)		
Spinal Cord	(1)	(0)	(0)	(0)	
Hemorrhage	1 (100%)	, ,		,	
RESPIRATORY SYSTEM  Lung Hematopoietic Cell Proliferation	(50)	(50) 1 (2%)	(50)	(50)	
Inflammation, Granulomatous				1 (2%)	
Inflammation, Focal, Chronic	1 (2%)				
Inflammation, Chronic Metaplasia, Osseous	2 (4%) 1 (2%)		1 (2%)	1 (2%)	
Necrosis	1 (270)		1 (2%)	1 (276)	
Alveolar Epithelium, Hyperplasia	2 (4%)	5 (10%)	2 (4%)		
Alveolus, Infiltration Cellular, Histiocyte	1 (2%)	1 (2%)	1 (2%)	3 (6%)	
Vein, Thrombosis			2 (4%)		
Nose	(50)	(50)	(50)	(50)	
Inflammation, Suppurative	4 (00()	1 (2%)	0 (40()		
Inflammation, Chronic Glands, Hyperplasia	1 (2%) 1 (2%)		2 (4%)		
Glands, Hyperplasia Glands, Inflammation, Suppurative	I (∠%)		2 (4%)		
Nasolacrimal Duct, Infiltration Cellular,	3 (6%)	1 (2%)	2 (4%)	1 (2%)	
Polymorphonuclear		2 ( 12 ( )	4 (00()	4 (22()	
Olfactory Epithelium, Atrophy, Focal	1 (20/)	2 (4%)	1 (2%)	1 (2%)	
Respiratory Epithelium, Hyperplasia, Focal Respiratory Epithelium, Necrosis	1 (2%)		1 (2%)	1 (2%)	
respiratory Epitricilum, Necrosis			1 (2/0)		

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B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Vomeronasal Organ, Infiltration Cellular,	9 (18%)	11 (22%)	2 (4%)	5 (10%)	
Polymorphonuclear Pleura	(0)	(0)	(1)	(0)	
SPECIAL SENSES SYSTEM					
Eye	(49)	(50)	(49)	(50)	
Degeneration Cornea, Inflammation, Chronic Retrobulbar, Inflammation, Chronic	1 (2%) 1 (2%) 1 (2%)	1 (2%)		1 (2%)	
Harderian Gland Fibrosis	(49)	(50)	(50)	(50) 1 (2%)	
Hyperplasia, Focal	7 (14%)	4 (8%)	3 (6%)	5 (10%)	
JRINARY SYSTEM					
Kidney Hydronephrosis Hyperplasia, Lymphoid	(50) 1 (2%) 1 (2%)	(50) 1 (2%)	(50)	(50)	
Infarct Infiltration Cellular, Lymphoid	2 (4%)	1 (2%) 1 (2%)	1 (2%)		
Metaplasia, Osseous	1 (2%)	1 (2%)	1 (2%)	1 (2%)	
Mineralization Nephropathy Arteriole, Inflammation, Chronic	6 (12%) 35 (70%)	5 (10%) 23 (46%) 1 (2%)	1 (2%) 28 (56%)	3 (6%) 38 (76%)	
Artery, Inflammation, Chronic Glomerulus, Amyloid Deposition	1 (2%)	. (270)		1 (2%)	
Renal Tubule, Accumulation, Hyaline Droplet Renal Tubule, Cyst	1 (2%)	2 (4%)		1 (2%)	
Urinary Bladder Artery, Inflammation, Chronic	(50)	(50)	(50)	(50) 1 (2%)	

<sup>\*\*\*</sup> END OF REPORT \*\*\*